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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,603	07/01/2003	Colombe Chappey	11068-065-999	4793

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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

ART UNIT PAPER NUMBER

1648

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/612,603	Applicant(s) CHAPPEY ET AL.	
	Examiner Louise Humphrey, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 3-6 and 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-24, 26-30, 32-36 and 38-42 is/are rejected.
- 7) ☒ Claim(s) 7, 18, 25, 31, 37 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/19/04, 7/13/04, 1/</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's election filed on 06 January 2006.

Election/Restrictions

Applicant elects Group I, claims 1, 2, 7, 8, and 12-42, without traverse.

Claims 1-42 are pending. Claims 3-6 and 9-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Claims 1, 2, 7, 8, and 12-42 are examined in the instant application.

Information Disclosure Statement

Three initialed and dated copies of Applicant's IDS form 1449, filed on 19 May 2004, 13 July 2004, and 20 January 2005, are attached to the instant Office action.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP §608.01. See pages 13 and 18, for example.

Claim objections

Claim 7 is objected to because it refers to mutations identified by reference to the Tables in the specification. Where possible, claims are to be complete in themselves.

Art Unit: 1648

Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim." M.P.E.P. §2173.05(s). It is suggested that the claims be amended to include the mutations disclosed in Tables 1 and 4.

Claims 18, 25, 31, 37, and 38 are objected to for being dependent from rejected claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 38 depends upon itself.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 12, 22, 26, 36, and 42 are rejected under 35 U.S.C. §102(b) as being anticipated by Robinson *et al.* (2000).

Instant claims are directed to A method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with a protease inhibitor, comprising: detecting whether the protease encoded by said HIV-1 exhibits the presence or absence of a mutation associated with reduced susceptibility to treatment with said protease inhibitor at amino acid position 11, 32, 33, 34, 43, 46, 47, 48, 50, 54, 58, 71, 76, 79, 82, 83, 84, 91 or 95 of an amino acid sequence of said protease, wherein the presence of said mutation indicates that the HIV-1 has an increased likelihood of having reduced susceptibility to treatment with the protease inhibitor, with the proviso that said mutation is not V32I, M46I, M46L, I47V, I50V, I54L, I54M or I84V.

Robinson *et al.* teach a method for assessing the susceptibility of HIV-1 plasma isolates to protease inhibitors (Abstract), which assays for resistance to amprenavir by detecting mutations including I54V and V82A (page 1153, left column). Thus, the instant invention is anticipated by Robinson *et al.*

Claims 1, 2, 7, 8, 12, 14, 22, 26, and 42 are rejected under 35 U.S.C. §102(b) as being anticipated by Schmidt *et al.* (2000).

The instant invention is summarized above.

Schmidt *et al.* teach the analysis of viral genotype from patient samples by direct sequencing of the protease gene in order to characterize the resistance to amprenavir.

The resistance profile includes the mutations 32I, 33F, 54V, and 82A/F. Thus, the instant invention is anticipated by Schmidt *et al.*

Claims 1, 7, 12, 19, 22, 26, and 42 are rejected under 35 U.S.C. §102(b) as being anticipated by Deeks *et al.* (1999).

The instant invention is summarized above.

Deeks *et al.* teach the genotypic and phenotypic assays of protease inhibitor resistance. Deeks *et al.* further teach the mutations I54A/V, A71L, and V82A/F. See Table 1. Thus, the instant invention is anticipated by Deeks *et al.*

Claims 1, 7, 12, 21, 22, 29, 32, 33, 36, and 39-42 are rejected under 35 U.S.C. §102(b) as being anticipated by Carrillo *et al.* (1998).

The instant invention is summarized above.

Carrillo *et al.* teach the detection of mutations, especially I84V, T91S, and V32I, in HIV protease in the presence of increasing concentrations of a protease inhibitor (Abstract, Table 2, and page 7536, first paragraph). The amino acid sequence of protease clones discloses the amino acids 58Q, L76V, 79P, and V82A (Figure 2). Thus, the instant invention is anticipated by Carrillo *et al.*

Claims 1, 7, 12, 19, 22, 29, 30, 36, and 42 are rejected under 35 U.S.C. §102(b) as being anticipated by Condra *et al.* (1996).

The instant invention is summarized above.

Condra *et al.* teach the evaluation of viral isolates by tracing amino acid substitutions in the HIV proteases that develop resistance to a protease inhibitor (Abstract, Materials and Methods). Condra *et al.* specifically teach the amino acid mutations: I54V/A, Q58E, and V82A/F/T (Table 1). Thus, the instant invention is anticipated by Condra *et al.*

Claims 1, 7, 12, 23, 36, and 42 are rejected under 35 U.S.C. §102(b) as being anticipated by Croteau *et al.* (1996).

The instant invention is summarized above.

Croteau *et al.* teach the characterization of protease inhibitor-resistant HIV and the amino acid mutations: I84V/A, V32I, and V82I/A/F/T (Table 1 and Table 2). See entire document. Thus, the instant invention is anticipated by Croteau *et al.*

Claims 1, 7, 12, 15, 16, and 42 are rejected under 35 U.S.C. §102(b) as being anticipated by Jørgensen *et al.* (June 2001).

The instant invention is summarized above.

Jørgensen *et al.* publish the sequence of a viral strain that is resistant to protease inhibitors (Accession No. CAB94359) and disclose the amino acid mutation E34Q, which is also published on the HIV drug resistance database. Thus, the instant invention is anticipated by Jørgensen *et al.*

Claims 1, 7, 12, 24, 36, and 42 are rejected under 35 U.S.C. §102(b) as being anticipated by Mascolini (2000).

The instant invention is summarized above.

Mascolini teaches the results from studies of HIV drug resistance, which discloses the amino acid mutations, T91A, after increased exposure to a protease inhibitor. See *Tipranavir*. Thus, the instant invention is anticipated by Mascolini.

Claims 1, 7, 12, 22, 26-28, 32-36, and 42 are rejected under 35 U.S.C. §102(b) as being anticipated by Palmer *et al.* (1999).

The instant invention is summarized above.

Palmer *et al.* teaches the results from characterization of HIV strains with four resistance profiles for the protease, which includes the amino acid mutations, I54T/V, P79S, V82A, I84V. See page 662, Table 1. Thus, the instant invention is anticipated by Palmer *et al.*

Claims 1, 7, 12, 13, 16, and 42 are rejected under 35 U.S.C. §102(b) as being anticipated by Colonno *et al.* (2000).

The instant invention is summarized above.

Colonno *et al.* publish the sequencing data from clinical viral isolates and submit the amino acid mutation, V11I, along with other mutations that are associated with resistance to nelfinavir, to the HIV Drug Resistance Database. Thus, the instant invention is anticipated by Colonno *et al.*

Claims 1, 7, 12, 14, 17, 20, 22, 26-28, 36, and 42 are rejected under 35 U.S.C. §102(a) as being anticipated by Kempf *et al.* (August 2001).

The instant invention is summarized above.

Kempf *et al.* teach the correlation of genotypic changes in HIV protease with reduced susceptibility to a protease inhibitor (Abstract). Kempf *et al.* specifically teach the mutations: L33F, K43T, I54L/T/V, A71I/L/T/V, V82A/F/T, and I84V (Abstract, Table 3, Table 4 and the paragraph bridging pages 7467-7468). Kempf *et al.* further predict that with larger sample sizes, other mutations, at amino acid positions 73, 43, 93, 58 and 33, might be found to be associated with reduced susceptibility (Discussion, page 7467, last paragraph). Thus, the instant invention is anticipated by Kempf *et al.*

Claims 1, 7, 12, 15, 16, and 42 are rejected under 35 U.S.C. §102(a) as being anticipated by Beerenwinkel *et al.* (June 2002).

The instant invention is summarized above.

Beerenwinkel *et al.* publish the sequence of a viral strain that is resistant to protease inhibitors (Accession No. AAK32197) and disclose the amino acid mutation C95F, which is also published on the HIV drug resistance database. Thus, the instant invention is anticipated by Beerenwinkel *et al.*

Claims 32 and 33 are inherently anticipated by every wild type strain of HIV because the limitation reads on the naturally occurring proline at position 79.

Remarks


Claims 18, 25, 31, 37, and 38 are free of prior art of the record, none of which teaches or fairly suggests the specific amino acid substitutions as recited.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D., whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902.

Louise Humphrey, Ph.D.
Patent Examiner
1 February 2006


JEFFREY STUCKER
PRIMARY EXAMINER